REMARKS

I. The Claims Are Supported by the Specification

The Examiner rejects claims 186, 189-194 and 199-206 under 35 U.S.C. § 112, first paragraph as allegedly containing new matter and allegedly failing to comply with the written description requirement. In particular, the Examiner states "the specification as originally filed does not envision composition that consisting essentially of." (Office Action, pg. 3). Applicants respectfully disagree. Nonetheless, Applicants herein amend Claims 186, 200 and 202 without acquiescing to the Examiner's arguments and solely to further their business interests and prosecution of the application, while reserving the right to file the original, or similar, claims in the future. Amended Claims 186 and 200 to recite the phrase "consisting of" rather than "consisting essentially of." Support for the use of compositions consisting of the recited components can be found in the specification, for example, on page 29, lines 5-8, which states:

> "In alternative embodiments of the present invention, the formulations comprise from about 5 vol. % of TWEEN 80, from about 8 vol. % of ethanol, from about 1 vol. % of CPC, about 64 vol. % of oil (e.g., soybean oil), and about 22 vol. % of DiH2O (designated herein as W805EC)."

Claims 186 and 200 consist of the above described components. Claim 202 further consists of EDTA. The specification describes that EDTA can be included in any of the described compositions (See e.g., specification, page 23). As such, the Applicants submit that the claims contain no new matter and are supported by adequate written description.

II. The Claims are Definite

The Examiner rejects Claim 203 under 35 U.S.C. 112, second paragraph, as allegedly indefinite. In particular, the Examiner states "It is unclear how the % amount of the cetylpyridinium chloride is compared to it self." (Office Action, pg. 4). Applicants respectfully disagree. Nonetheless, Applicants herein cancel Claim 203 without acquiescing to the Examiner's arguments and solely to further their business interests and prosecution of the application, while reserving the right to file the original, or similar, claims in the future. As such, the rejection is moot.

III. The Claims are Not Obvious

The Examiner rejected Claims 186-194, 197 and 199-203 under 35 U.S.C. §103(a) as allegedly being unpatentable over Libin (U.S. Pat. No. 5,855,872) in view of Stroud et al. (U.S. Pat. No. 6,231,837); Claims 186-188, 191, 193, 194 and 197-200, 202 and 203 as allegedly being unpatentable over Asculai et al. (US Pat. No. 4,020,183) in view of Keith et al. (US Pat No. 4,350,707); and Claims 202 and 203 as allegedly being obvious in light of Libin in view of Thomsen et al (US 6.342,537; hereinafter Thomsen I) or Thomsen et al. (US 5,981,605; hereinafter Thomsen II) in view of Asculai. Applicants respectfully disagree.

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness.[1] A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.[2] An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art.[3]

Applicants respectfully submit that the cited references, individually or combined, do not teach or suggest each element of the claimed invention. Moreover, Applicants respectfully submit that the limitations of the amended claims exclude the compositions of the cited references. Applicants further submit that the references do not provide a motivation to combine the references with an expectation of success.

A) The Cited References Do Not Teach or Suggest All Limitations of the Claims

Applicants previously noted that the prior claims, reciting "consisting essentially of," excluded the prior art. The Examiner did not agree with this, taking the position that "consisting essentially of" has a meaning more similar to "comprising." Applicants respectfully disagree. However, as described above, Applicants have amended the Claims to recite *consisting of*, rather than consisting essentially of.

Applicants respectfully submit that the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus

[1] See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).
[2] In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).
[3] In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, the nanoemulsion *consisting of* 1) a discontinuous oil phase; 2) an aqueous phase; 3) 3-15% by volume ethanol; and 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume halogen-containing compound (e.g., as recited in Claim 186). Similarly, the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition *consisting of*: 1) 50-80% by volume oil; 2) distilled water; 3) 3-15% by volume ethanol; 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume cetylpyridinium chloride (e.g., as recited in Claim 200); nor a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition *consisting of*: 1) 3-15% by volume surfactant; 2) 3-15% by volume ethanol; 3) 50-80% by volume oil; 4) cetylpyridinium chloride; 5) distilled water; and 6) ethylenediaminetetraacetic acid (e.g., as recited in Claim 202).

Thus, the cited references, individually or in combination, fail to teach or suggest all the claim limitations.

Applicants further submit that the compositions and methods disclosed by the cited references are excluded by the limitations of the amended claims. For example, the presently claimed invention requires that the compositions *consist of* the recited components. The compositions of Libin specifically require elements (e.g., an antimicrobial agent such as Triclosan) that are specifically excluded by the presently claimed invention. In particular, Libin states:

> "dispersed in the emulsion is an antimicrobial composite created by two distinct antimicrobial agents, one being non-cationic and the other cationic. When combined, the agents act synergistically to promote their delivery and retention on the HSV infected tissues.
>
> Non-cationic antibacterial agents, which are particularly desirable in terms of effectiveness and safety are halogenated di-phenyl ethers, preferably Ticlosan." Libin, column 3, 2nd-3rd paragraph.

Thus, Libin is not suitable as a reference because it requires a component excluded by the presently claimed invention. Likewise, Stround, is directed to compositions for sunless tanning, requires elements (e.g., skin darkening agents) that are specifically excluded by the present

invention. Thus, Libin, alone or in combination with Stroud, does not teach a composition that *consists of* the components of the presently claimed compositions. Likewise, neither Thomsen or Mulder provide such a composition. Thomsen specifically excludes surfactants from the recited compositions (See e.g., column 9, last full paragraph).

Likewise, neither Keith nor Asculai teach or suggest a composition *consisting of* the recited components. Indeed, the compositions of Keith specifically require butylated hydroxytoluene, which is excluded by the compositions of the present invention. In addition, neither Asculai nor Keith, alone or in combination teach the claim element of cetylpyridinium chloride. Indeed, Asculai only mentions cetylpyridinium chloride in the background discussion as the work of others and does not provide or suggest the use of any compositions comprising cetylpyridinium chloride in its own formulations. Thus, this is an additional and independent reason that Asculai, alone or in combination with Keith, does not teach a composition that *consists of* the components of the presently claimed compositions.

B) The cited references do not provide a motivation to combine the references with a reasonable expectation of success

The Applicants further submit that the Examiner has not demonstrated a motivation to combine the reference with a reasonable expectation of success. Existing treatment for individuals infected with *Herpes simplex I* (HSV1) are often systemic, thus carrying the risk of side effects. In addition, many viruses develop resistance to conventional anti-viral treatments. The existing commercial treatments do not sufficiently address these issues. New treatments are needed. The methods of the presently claimed invention utilize specific nanoemulsion formulations having anti-HSV1 activity.

One of skill in the art faced with the problem of developing the specific nanoemulsion formulations of the presently claimed invention would <u>not</u> have had a limited number of predictable options to test, they would have had many. There are not a finite number of predictable choices or combinations of choices for formulating effective nanoemulsions with the activity of killing HSV1 after topical activation. There are many, many possible combinations of many components one could try. It would take innumerable amounts of time and resources to test the possible combinations.

For example, the Libin reference cited by the Examiner requires that all of the recited compositions include the antiviral agent Tricosan. There is no teaching that effective compositions could be generated without the additional of Tricosan to the described compositions. Indeed, one of ordinary skill in the art would believe that removal of Tricosan would result in compositions lacking antiviral activity because Tricosan in an anti-viral agent. There is no specific guidance in Libin that would have led an ordinary artisan to select either the ingredients of the claimed invention (to the exclusion of other ingredients) and the recited concentrations, among innumerable other possible modifications.

Likewise, the additional references cited by the Examiner contain ingredients that, if removed, would be likely to render the compositions inactive. Thus, one of ordinary skill in the art would not expect the compositions described by the references cited by the Examiner to be functional if ingredients not found in the compositions used in the presently claimed invention are removed. This is because the ingredients that would need to be removed are ingredients with anti-HSV1 activity.

Thus, Applicants respectfully request that the rejections made under 35 U.S.C. § 103 be reconsidered and withdrawn on the grounds that the references, individually or in combination, do not provide a motivation to combine the references with a reasonable expectation of success, and even if improperly combined, the references do not teach or suggest each and every element of the claimed invention.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants have addressed all grounds for rejection and Applicants' claims should be passed to allowance. Reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: August 14, 2009

/Tanya A. Arenson/

Tanya A. Arenson, Reg. No.: 47,391
CASIMIR JONES, S.C.
440 Science Drive, Suite 203
Madison, Wisconsin 53711
608/218-6900